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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/697,703
Filing Date: October 31, 2003
Appellant(s): BOSCH ET AL.

Michele M. Simkin

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed Apr. 7, 2011 appealing from the Office action mailed Nov. 9, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

- Application No. 10/697,716, (Appeal No. 2011-002039);
- Application No. 10/768,194 (Appeal No. 2011-001850, decided May 25, 2011; decision attached);
- Application No. 11/376,553, (Appeal No. 2010-012147); and
- Application No. 11/436,887, (Appeal No. 2011-002635).

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-95 are pending.

Claims 12, 13, 27, 32-35, 39, 41-43, and 45-95 are withdrawn.

Claims 1-11, 14-26, 28-31, 36-38, 40, and 44 are pending and rejected.

(4) Status of Amendments

No new claim amendments have been submitted.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant's statement of the grounds of rejection to be reviewed on appeal is accurate. Every ground of rejection set forth in the Office action from which the appeal is taken is being maintained by the examiner.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

USPN 5552160	Liversidge et al.	09-1996
USPN 6017932	Singh et al.	01-2000

The Merck Index, 12th ed. 1996, Merck & Co., pp. 2518 and 2531.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. Claims 1-11, 14-26, 28-31, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. (USPN 5,552,160) in view of Singh et al. (USPN 6,017,932).

Liversidge et al. disclose pharmaceutical compositions which exhibit reduced gastric irritation and hastened onset of action, comprising dispersible particles consisting essentially of a crystalline NSAID (non-steroidal anti-inflammatory drug) having a surface modifier adsorbed on the surface thereof, in an amount sufficient to maintain an effective average particle size of less than about 400 nm (abstract; col. 1, lines 61-64).

The nanoparticulate NSAID exists in a discrete, crystalline phase, and is poorly soluble (col. 2, lines 39-58). Suitable surface stabilizers do not chemically react with the NSAID and can include, *inter alia*, polyvinyl pyrrolidone (PVP) or tyloxapol (col. 3, lines 57-58; col. 4, lines 10-19). At least 90% of the particles have an average particle size of less than about 400 nm (col. 4, lines 26-27).

The relative amount of the NSAID and the surface modifier can vary widely, and the optimal amount of the surface modifier can depend, for example, upon the particular NSAID and surface modifier selected (col. 6, lines 5-15). Compositions comprising the

surface-stabilized nanoparticles can be administered orally, for example, as a liquid dispersion spray-coated onto sugar spheres (col. 6, line 56 to col. 7, line 11).

Liversidge et al. exemplify compositions comprising proportions of NSAID to surface modifier (naproxen, Examples 1-2; ibuprofen, Examples 3-8; and indomethacin, Examples 9-12) falling within the ranges recited by claims 7 and 8. Also disclosed are examples of suitable excipients which can be included in the compositions are disclosed (col. 3, lines 34-56), noting that two or more surface modifiers can be used in combination, as recited by claim 9. The composition can be considered bioadhesive because the surface modifiers adhere to the surface of the NSAID, but do not chemically bond to the NSAID (see col. 3, lines 25-27), as recited by claim 15.

Further, the nanoparticulate NSAID compositions of Liversidge et al. have decreased T_{max}, increased C_{max}, and increased AUC, when compared to larger particles (see col. 9, lines 1-20), as recited by claims 16-21, 25, and 26. In particular, the size of the control particles was between 20-30 microns (col. 7, lines 35- 38), while the size of the nanoparticles was between 240-300 nm (col. 7, lines 32-34). A simple screening process was used to determine compatible surface modifiers with NSAIDs, and also the amounts of surface modifier and NSAID, which can be adjusted by known variables (col. 6, lines 5-55).

However, Liversidge et al. do not expressly identify nimesulide as a suitable NSAID.

Singh et al. disclose pharmaceutical compositions with enhanced bioavailability of non-steroidal anti-inflammatory drugs (NSAIDs), as compared to known

compositions, with the benefits of reducing both the dosage required and dose-related side effects (abstract). Preferably, the NSAID is nimesulide, nabumetone, tepoxalin, flosulide and/or derivatives thereof (col. 1, lines 10-12). In particular, Singh et al. exemplify tablets comprising nimesulide and polyvinyl pyrrolidone (PVP, a.k.a. povidone) as an excipient (Examples III, IV, and VI), as recited by claim 5.

One of ordinary skill in the art would have been motivated to modify the compositions disclosed by Liversidge et al. by incorporating nimesulide as the NSAID for several reasons. First, Singh et al. disclose distinct advantages of nimesulide, such as its better gastric tolerance than other common NSAIDs; high efficacy against cancer pain; and comparable or superior analgesia to other NSAIDs like diclofenac or piroxicam (col. 2, lines 28-36). Singh et al. teach that nimesulide exhibits potency similar to or greater than that of indomethacin, diclofenac, piroxicam and ibuprofen in standard animal models of inflammation; and animal studies have suggested that nimesulide is less ulcerogenic than aspirin, indomethacin, naproxen, piroxicam and ibuprofen (col. 2, lines 44-66).

Liversidge et al. identify nabumetone, diclofenac, piroxicam, indomethacin, ibuprofen, aspirin, and naproxen as suitable NSAIDs (col. 3, lines 1-20). Singh's focus on four specific NSAIDs, including nabumetone and nimesulide, and the particular advantages associated with the latter, strongly suggests to the skilled artisan that nimesulide could be successfully formulated as taught by Liversidge et al.

Thus, nimesulide as taught by Singh et al. formulated as taught by Liversidge et al., having an average particle size of less than 400 nm and a surface modifier such as

PVP or tyloxapol adsorbed on the surface thereof, reads on the composition recited by claims 1 and 3. Liversidge et al. disclose that the NSAID is in crystalline form, as recited by claim 2. Both references disclose the oral route of administration, as recited by claim 4; additional excipients, as recited by claim 6; and polyvinylpyrrolidone (PVP), as recited by claims 10 and 11. Liversidge et al. discloses tyloxapol as a preferred surface modifier (col. 3, lines 57-58), as recited by claim 14.

Nimesulide compositions formulated as taught by Liversidge et al. would be reasonably expected to exhibit similarly decreased T_{max} and increased C_{max} and AUC, when compared to non-nanoparticle formulations of nimesulide, as recited by claims 16-21, 25, and 26. Because products of identical chemical composition cannot have mutually exclusive properties, the compositions of Liversidge et al. as modified by Singh et al. would also be expected to possess the absorption properties recited by claims 22-24, and the redispersal properties recited by claims 28-31. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the composition, the properties applicant claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

While neither reference explicitly discloses sterile-filtered compositions, as recited by claim 44, this limitation is implicit in the disclosed methods of preparing the formulations for administration to humans, since it is well-known in the medicinal arts that pharmaceutical compositions must be free of biological and chemical contaminants in order to be safe and effective.

A skilled artisan would have been motivated to substitute less-ulcerogenic nimesulide as taught by Singh et al. (col. 2, lines 65-67) into the surface-modified NSAID compositions of Liversidge et al. to obtain the advantage of even further reduction of gastric irritation (col. 2, lines 18-19). A skilled artisan would expect the combination to work, because Singh et al. teaches that nimesulide is poorly soluble and dispersible in at least one liquid medium (col. 3, lines 54-61) as required by Liversidge et al. (col. 2, lines 52-54).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate nimesulide, as taught by Singh et al., as an NSAID nanoparticle with a surface modifier adsorbed thereon, as taught by Liversidge et al. with a reasonable expectation of success, because the references disclose the advantages of improving the bioavailability of poorly-soluble NSAID drugs, hastening the onset of therapeutic effects, and reducing side effects.

2. Claims 1, 36-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. (USPN 5,552,160) in view of Singh et al. (USPN 6,017,932) as applied to claims 1-11, 14-26, 28-31, and 44 above, and further in view of *The Merck Index* (cited in the previous action).

As discussed above, **Liversidge et al**. disclose pharmaceutical compositions comprising dispersible particles consisting essentially of a crystalline NSAID (non-steroidal anti-inflammatory drug) having a surface modifier adsorbed on the surface

thereof, in an amount sufficient to maintain an effective average particle size of less than about 400 nm (abstract; col. 1, lines 61-64).

The nanoparticulate NSAID exists in a discrete, crystalline phase, and is poorly soluble (col. 2, lines 39-58). Suitable surface stabilizers do not chemically react with the NSAID and include, *inter alia*, polyvinyl pyrrolidone (PVP) and tyloxapol (col. 4, lines 10-19). At least 90% of the particles have an average particle size of less than about 400 nm (col. 4, lines 26-27).

However, Liversidge et al. do not expressly identify nimesulide as a suitable NSAID.

Singh et al. disclose pharmaceutical compositions with enhanced bioavailability of non-steroidal anti-inflammatory drugs (NSAIDs), as compared to known compositions of the drugs, with the benefits of reducing both the dosage required and dose-related side effects (abstract). Preferably, the NSAID is nimesulide, nabumetone, tepoxalin, flosulide and/or derivatives thereof (col. 1, lines 10-12). In particular, Singh et al. exemplify tablets comprising nimesulide and polyvinyl pyrrolidone (PVP, a.k.a. povidone) as an excipient (Examples III, IV, and VI), as recited by claim 5.

Liversidge et al. identify nabumetone, diclofenac, piroxicam, indomethacin, ibuprofen, aspirin, and naproxen as suitable NSAIDs (col. 3, lines 1-20). Singh's focus on four specific NSAIDs, including nabumetone and nimesulide, and the particular advantages associated with the latter, strongly suggests to the skilled artisan that nimesulide could be successfully formulated as taught by Liversidge et al. Thus, nimesulide as taught by Singh et al. formulated as taught by Liversidge et al., having an

average particle size of less than 400 nm and a surface modifier such as PVP or tyloxapol adsorbed on the surface thereof, reads on the composition recited by claim 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate nimesulide, as taught by Singh et al., as an NSAID nanoparticle with a surface modifier adsorbed thereon, as taught by Liversidge et al. with a reasonable expectation of success, because the references disclose the advantages of improving the bioavailability of poorly-soluble NSAID drugs, hastening the onset of therapeutic effects, and reducing side effects.

However, Liversidge et al. and Singh et al. do not disclose compositions further comprising a non-nimesulide active agent, specifically the analgesic codeine, as recited by claims 36-38 and 40.

Singh et al. teach that nimesulide has analgesic properties (col. 2, lines 44-54).

In addition, as disclosed by **Merck**, it is well-known in the art that codeine has analgesic properties (p. 2531, left column). As recognized by MPEP §2144.06, “it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Here, both nimesulide as disclosed by Singh et al. and codeine as taught by Merck were known to be administered in pharmaceutical compositions to produce

analgesia (pain relief). Thus, it would have been predictable to a skilled artisan to combine two analgesics with a reasonable expectation of success.

(10) Response to Argument

Appellant contends that the references do not teach each and every limitation of the claimed invention, because Liversidge et al. teach particles less than 400 nm in size (Brief p. 17). However, claim 1 recites an average particle size of less than 2000 nm, which encompasses particles less than 400 nm, because 400 is less than 2000. Further, claims 3, 29, and 31 explicitly recite various average particle sizes less than 2000 nm, including less than 400 nm.

In addition, Appellant contends that claims 16-26, which recite certain biological properties of the claimed composition – T_{max}, C_{max}, AUC, and absorption – were rejected under an improper inherency rationale, because the examiner has not established that the claimed composition is the same as the prior art; instead, the rejection is based on the rationale that the compositions of Liversidge et al. as modified by Singh et al. would result in the claimed compositions (Brief, pp. 19-20).

However, the properties recited by claims 16-26 do not further physically or structurally limit the composition of claim 1, but rather describe certain properties thereof. It follows that, if it would have been *prima facie* obvious to modify Liversidge in view of Singh to arrive at the claimed compositions, the properties of those compositions would have been inherently present therein, because products of identical

composition cannot have mutually exclusive properties. Therefore, if the prior art teaches the identical composition, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In addition, as recognized by MPEP §2112.01, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus, the question turns on whether the rationale to combine the cited references to arrive at the claimed compositions is sufficient to establish a *prima facie* case of obviousness.

Appellant contends there is no reason to combine the cited references because there is no reason to solve a problem that has already been solved, namely, poor bioavailability, which is solved by either Liversidge et al. or Singh et al. alone (Brief, pp. 14-15).

Liversidge et al. teach methods of improving bioavailability of NSAIDs by having a surface modifier adsorbed on the surface thereof, in an amount sufficient to maintain an effective average particle size of less than 400 nm (abstract). Liversidge et al. measure relative bioavailability by AUC (area under the curve), which is improved in Formulation I as compared to control (col. 8, line 61 to col. 9, line 19).

Singh et al. teach methods of improving bioavailability of NSAIDs by formulating the active agent with piperine (abstract). Singh et al. measure bioavailability by plasma

concentration at 90 minutes post-treatment, which is higher when nimesulide is formulated with piperine than when nimesulide is administered alone (col. 9, line 16 to col. 10, line 16).

Because neither reference discloses 100% bioavailability of the NSAID, it follows that further improvement in bioavailability is possible. In addition, Singh et al. disclose that “[v]arious attempts to improve the solubility and hence the bio-availability of nimesulide have been reported,” followed by a lengthy literature review (col. 3, line 54 to col. 5, line 10). This suggests that the problem of nimesulide bioavailability is never completely “solved," such that further refinements and improvements remain possible.

Appellant contends that there is no articulated reason why a skilled artisan would have subjected nimesulide as formulated by Singh to Liversidge's particle size reduction process; and that doing so would change the principle of operation of Singh, which relies on the synergistic effect of nimesulide and piperine (Brief, pp. 15-16).

To clarify, the rejection is based on Liversidge et al. as the primary reference, which teaches a method of improving the solubility and bioavailability of poorly soluble NSAIDs, modified in view of Singh et al., the secondary reference, which teaches that nimesulide is a poorly soluble NSAID. However, the NSAID bioavailability improvement methods of Liversidge et al. and Singh et al. are not mutually exclusive and could be combined. Liversidge et al. modify the NSAID particles directly, while Singh et al. modify the excipient(s) with which the NSAID is formulated. Combining the two methods would result in the claimed compositions, which do not exclude piperine.

In this respect, the instant claims recite a composition *comprising* nimesulide particles. As recognized by MPEP §2111.03, the transitional term "comprising," which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Appellant contends that the articulated reason to combine the teachings of the cited references is defective. Specifically, Singh's teaching that nimesulide exhibits better gastric tolerance and less ulcerogenic properties than other NSAIDs would have discouraged, rather than motivated, a skilled artisan to subject nimesulide to the expensive, time-consuming particle size reduction process taught by Liversidge (Brief, p. 16).

As noted above, neither reference discloses 100% bioavailability of the NSAID; thus, a skilled artisan would have understood that further improvements were possible. In fact, a skilled artisan would have predicted superior results with an NSAID composition comprising a threefold advantage by (1) employing an NSAID with better gastric tolerance (2) formulated as nanoparticles with a surface modifier to improve bioavailability (3) with a solubility-enhancing excipient. A skilled artisan would have been motivated to select an NSAID known to be less ulcerogenic than others, because

such a drug would be preferred for gastric-sensitive patients who could not tolerate other NSAIDs.

Appellant contends that there would have been no reasonable expectation of success in combining the cited references, because the examiner did not establish why the mere fact of nimesulide's poor solubility would give rise to such an expectation, when nimesulide does not share any structural similarity with the NSAIDs exemplified by Liversidge (Brief, pp. 18-19).

Nimesulide's poor solubility would have given a skilled artisan a reasonable expectation of success because Liversidge et al. teach that not just any NSAID is suitable; an NSAID which is poorly soluble is required (col. 2, lines 52-65):

> The invention can be practiced with a wide variety of NSAIDs. However, the NSAID must be poorly soluble and dispersible in at least one liquid medium. By "poorly soluble" it is meant that the NSAID has a solubility in the liquid dispersion medium, e.g., water, of less than about 10 mg/ml, and preferably of less than about 1 mg/ml at processing temperature, e.g., room temperature. The preferred liquid dispersion medium is water.

That nimesulide is structurally dissimilar to the compounds exemplified by Liversidge et al. is immaterial because, as noted by Appellant (Brief, pp. 16-17), approximately forty suitable NSAIDs are identified (col. 3, lines 3-18) by their properties of being poorly soluble and acidic or non-acidic, irrespective of their structure. Singh et al. teach that nimesulide is a poorly soluble NSAID, and contains a sulfonanilide moiety as the acidic group (col. 1, lines 62-65). Thus, a skilled artisan would have had a reasonable expectation of success utilizing nimesulide in the methods of Liversidge et al.

In addition, as recognized by MPEP § 2123, patents are relevant as prior art for all they contain. “The use of patents as references is not limited to what the patentees

describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

With respect to claim 44, drawn to the composition of claim 1 which has been sterile-filtered, Appellant contends that the examiner's assertion that "it is well-known in the medicinal arts that pharmaceutical compositions must be free of biological and chemical contaminants in order to be safe and effective" is an improper reliance on common knowledge which requires the evidentiary support of a prior art publication (Remarks, p. 20).

However, it is not improper to rely on knowledge common to those of ordinary skill in the art to modify a reference. *Wyers v. Master Lock Co.* (95 USPQ 2d 1525, Fed. Cir. 2010) recognizes that the Supreme Court's decision in *KSR v. Teleflex* "instructs

courts to take a more 'expansive and flexible approach' in determining whether a patented invention was obvious at the time it was made . . . . In particular, the Court emphasized the role of "common sense": "[r]igid preventative rules that deny factfinders recourse to common sense … are neither necessary under our case law nor consistent with it." 95 USPQ 2d 1525 at 1531.

Accordingly, the Board recently affirmed a similar rationale, namely that "sterilization of a formulation provides additional benefits to its recipients" (Appeal 2011-001850, pp. 9-10). A motivation to combine the cited references need only be supported by an articulated reasoning with rational underpinnings. See *In re Kahn*, 441 F.3d 977, 989 (Fed. Cir. 2006).

With respect to the rejection of claims 36-38 and 40 over Liversidge et al. in view of Singh et al. and *The Merck Index*, Appellant contends that no articulated reasoning has been established explaining why a skilled artisan would have included a secondary analgesic in a composition comprising nimesulide, which already has analgesic properties (Brief, p. 21).

The compositions of Singh et al. are not limited to the formulation examples, but may comprise one or more pharmaceutically acceptable doses of NSAIDs or derivatives thereof or a mixture thereof (col. 11, line 63 to col. 13, line 14). NSAIDs were known as analgesic-antipyretic and anti-inflammatory agents (col. 1, lines 55-57). Thus, Singh et al. disclose compositions comprising one or more analgesics. While codeine is not an NSAID, *Merck* discloses that codeine was a known analgesic (p. 2531, left col.).

As noted above, MPEP §2144.06 recognizes that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Finally, Appellant contends that, in the absence of a valid reason to combine the cited references, the examiner's rationale amounts to "obvious to try," and/or fully informed by the benefit of improper hindsight (Brief, p. 17, p. 22).

While any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The motivation to combine the cited references is not that it would have been obvious to try, but that it would have been obvious to combine prior art elements to yield predictable results. As recognized by MPEP §2143, combining prior art elements according to known methods to yield predictable results would motivate the skilled artisan to modify the references with a reasonable expectation of success. The rationale to support a conclusion of *prima facie* obviousness is that all the claimed elements were

known in the prior art, and a skilled artisan could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. See *KSR Int'l Co. v. Teleflex Inc.* (550 U.S. 398, 409).

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/SARA E TOWNSLEY/

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/Brian-Yong S Kwon/

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